US Army Medical Research and Materiel

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Dip-stick Assay for C-reactive Protein

This invention provides a method for detecting tissue injury, inflammation or infection in a subject by measuring levels of C-reactive protein (CRP) in a biological sample. The method involves binding an antibody against CRP to a solid support, such as a dip-stick and membrane; incubating the dip-stick with the sample under conditions where antibody-antigen complexes form; incubating the dip-stick with an anti-CRP antibody conjugated to a detectable substance which produces a signal; and visually detecting the signal, which is proportional to the amount of CRP in the sample.

CRP is a prototypic acute phase protein in humans that increases rapidly in concentration as a result of tissue injury, inflammation or infection. The normal range of serum CRP is 0.08-3 mg/l. However, CRP levels can increase between 100-1000-fold during an inflammatory response. Elevated serum levels of CRP are seen 6-12 hours after an inflammatory stimulus, and maximum levels are reached within 48-72 hours. Generally, CRP levels will return to normal 10 - 55 days after remission of inflammation. Because the accumulation of CRP in serum closely parallels the course of inflammation and tissue injury, CRP has been used as a diagnostic tool to detect inflammation and to monitor the clinical course of various diseases, including rheumatoid arthritis and cardiac [illegible]. Automated, quantitative determination of CRP can be performed by highly trained technicians; these tests typically require a turnaround time of a day or so. This rapid visual assay is simple, and requires no specific instrumentation.

The assay could be used to detect a bacterial infection and to monitor CRP levels during therapy, thus providing an indication if the therapy is successful.

Features and advantages:

- **Provides a rapid, semi-quantitative test method for determining levels of CRP in biological fluids**
- **Fast, accurate assay can be performed at patient location**
- **Sophisticated equipment is not required**
- **Could be used to detect infection indicated by CRP levels at or above 10 mg/l**
- **Requires only 5 ul of sample, compared to other assays**

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